



1615 #8
APR 29 2002
Docket No. MCP-0271

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Bunick & Luber
Serial No. : 09/752,601 Art Unit 1615
Filed : 12/29/00 Examiner: J. Spear
Title : Soft Tableted Prepared by Post Compression Heating

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April 16, 2002
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(Signature)

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Honorable Commissioner of Patents
Washington, D.C. 20231

RESPONSE

Dear Sir:

This paper is in response to the Office Action of January 16, 2002. Reconsideration of the above-identified application is respectfully requested in view of the following remarks.

This application contains claims 1-23. Claims 1, 14 and 19 are independent. Claim 1 recites a process for preparing a chewable or disintegrative tablet, comprising forming a tablet having a friability of less than about 2% from a mixture comprising a pharmaceutically active ingredient, an excipient in the form of a hydrate, and a water-swellable excipient, and then applying sufficient energy to the tablet for a sufficient time to decrease the hardness of the tablet by at least about 20%.

Claim 14 recites a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing, comprising a) a pharmaceutically active ingredient, b) an excipient at

least partially in the form of a hydrate, and c) a water-swellable excipient that is at least partially hydrated.

Claim 19 recites a tablet comprising: a) a pharmaceutically active ingredient, b) dextrose monohydrate, and c) crospovidone.

Applicants note that claim 2 contains allowable subject matter.

Claims 1 and 3-13 stand rejected under 35 U.S.C. §112, first paragraph, as enabling only for providing energy in the form of heat. The Examiner argues that the specification is not enabling for other sources of energy.

Applicants disagree. In the passage of the specification cited by the Examiner, applicants state “[p]referably, energy is applied to the tablet in the form of heat or electromagnetic radiation, such as microwaves. More preferably, energy is applied in the form of heat.” See page 6, lines 10-11. The disclosure is indeed enabling for more than energy in the form of heat. Electromagnetic radiation, including microwaves, is also given as an example of an energy source. Accordingly, withdrawal of the rejection under Section 112 is respectfully requested.

On the merits, claims 14-23 stand rejected under 35 U.S.C. §102(e) as anticipated by Danielson. The Examiner argues this reference discloses in column 5, lines 1-26, a tablet comprising ingredients falling within applicants’ claims, and therefore Danielson’s tablet would inherently possess the same properties as the claimed tablet.

Applicants again disagree. Danielson’s example discloses chewable tablets comprising famotidine as the active ingredient, which is granulated in a solution containing povidone, then coated with a taste-masking polymer. The coated granules are then compounded with aspartame, maltodextrin, mannitol, microcrystalline cellulose, red-iron oxide, sodium starch glycolate, peppermint, corn starch and magnesium stearate.

Claim 14 requires the presence of a water-swellable excipient that is at least partially hydrated. Although the Danielson patent discloses the use of water-swellable excipients, it does not disclose the use of water-swellable excipients that are at least partially hydrated. Nor could it. Danielson does not disclose the application of energy to the tablets made in his example. This is the step of the present invention that converts the water-swellable excipient into a water-swellable excipient that is at least partially hydrated. See applicants’ specification on page 6, lines 15-24. Accordingly, the rejection over Danielson is without basis and should be withdrawn.

Serial No. 09/752,601

Applicants respectfully request allowance of claims 1-23.

Respectfully submitted,

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